

Summary of product characteristics for a biocidal product

Product name: Protect sensation

Product type(s): PT14 - Rodenticides (Pest control)

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Authorisation number: FR-2019-0032

R4BP 3 asset reference number: FR-0019220-0000

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Administrative information

1.1. Trade names of the product

Protect sensation

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Bábolna Bioenvironmental Centre Ltd.
	Address	Szállás u. 6. H-1107 Budapest Hungary
Authorisation number	FR-2019-0032	
R4BP 3 asset reference number	FR-0019220-0000	
Date of the authorisation	11/04/2019	
Expiry date of the authorisation	17/01/2026	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Bábolna Bioenvironmental Centre Ltd.
Address of the manufacturer	Szállás u. 6. H-1107 Budapest Hungary
Location of manufacturing sites	Dr Köves Janos utca 3. 2943 Bábolna Hungary

1.4. Manufacturer(s) of the active substance(s)

Active substance	12 - Bromadiolone
Name of the manufacturer	Babolna Bio Ltd
Address of the manufacturer	Szállás u. 6. 1107 Budapest Hungary
Location of manufacturing sites	Dr Tezza Srl / Tre Ponti 22 37050 St. Maria di Zevio Italy

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	Active Substance	28772-56-7	249-205-9	0,005

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	<p>May damage the unborn child.</p> <p>Causes damage to organs (blood) through prolonged or repeated exposure .</p>
Precautionary statements	<p>Keep out of reach of children.</p> <p>Obtain special instructions before use.</p> <p>Do not handle until all safety precautions have been read and understood.</p> <p>Do not get in eyes, on skin, or on clothing.</p> <p>Wash thoroughly after handling.</p> <p>Do no eat, drink or smoke when using this product.</p>

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

IF SWALLOWED: Immediately call a POISON CENTER or doctor.

IF exposed or concerned: Get medical .

Get medical if you feel unwell.

Store locked up.

Dispose of contents to and container in accordance with the local requirements / the instruction of the label.

4. Authorised use(s)

4.1 Use description

Use 1 - House mice and rats –trained professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: juveniles and adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: juveniles and adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: Roof rat Development stage: juveniles and adults</p>
Field(s) of use	<p>Indoor</p> <p>indoor</p>
Application method(s)	<p>Method: Bait application Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations - [Covered and protected baiting points]</p>
Application rate(s) and frequencies	<p>Application Rate: Rats (<i>Rattus norvegicus</i> and <i>Rattus rattus</i>) - High infestation: 200 g of bait per baiting point every 7 metres. - Low infestation: 200 g of bait per baiting point</p>

every 10 metres. Mice (*Mus musculus*) - One bait point of 50 g bait every 5 metres.
Dilution (%): 0
Number and timing of application:
Bait products:

Rats (*Rattus norvegicus* and *Rattus rattus*)
- High infestation: 200 g of bait per baiting point every 7 metres.
- Low infestation: 200 g of bait per baiting point every 10 metres.

Mice (*Mus musculus*)
- One bait point of 50 g bait every 5 metres.

Category(ies) of users

Trained professional

Pack sizes and packaging material

Minimum pack size of 3 kg.

(In France only : minimum pack size of 5 kg)

PROTECT SENSATION is supplied in loose blocks of 20, 25 or 50 g. Loose blocks are packed in:

- PP bucket (5 to 8 kg)
- PE bag (5 to 25 kg).

4.1.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.1.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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4.2 Use description

Use 2 - House mice and rats – trained professionals – outdoor around buildings

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use

Not relevant for rodenticides

Target organism(s) (including development stage)

Scientific name: *Mus musculus*
Common name: House mouse
Development stage: juveniles and adults

Scientific name: *Rattus norvegicus*
Common name: Brown rat
Development stage: juveniles and adults

Scientific name: *Rattus rattus*
Common name: Roof rat
Development stage: juveniles and adults

Field(s) of use

Outdoor

Outdoor around buildings

Application method(s)

Method: Bait application

Detailed description:

- Ready-to-use bait to be used in tamper-resistant bait stations.
- [Covered and protected baiting points]

Application rate(s) and frequencies

Application Rate: Rats (*Rattus norvegicus* and *Rattus rattus*) - High infestation: 200 g of bait per baiting point every 7 metres. - Low infestation: 200 g of bait per baiting point every 10 metres. Mice (*Mus musculus*) - One bait point of 50 g bait every 5 metres.

Dilution (%): 0

Number and timing of application:

Bait products:

Rats (*Rattus norvegicus* and *Rattus rattus*)

- High infestation: 200 g of bait per baiting point every 7 metres.

	<ul style="list-style-type: none"> - Low infestation: 200 g of bait per baiting point every 10 metres. <p>Mice (<i>Mus musculus</i>)</p> <ul style="list-style-type: none"> - One bait point of 50 g bait every 5 metres.
Category(ies) of users	Trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>(In France only : minimum pack size of 5 kg)</p> <p>PROTECT SENSATION is supplied in loose blocks of 20, 25 or 50 g. Loose blocks are packed in:</p> <ul style="list-style-type: none"> - PP bucket (5 to 8 kg) - PE bag (5 to 25 kg).

4.2.1 Use-specific instructions for use

<ul style="list-style-type: none"> - Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding. - Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt. - Remove the remaining product at the end of treatment period - [When available] Follow any additional instructions provided by the relevant code of best practice. - [For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].

4.2.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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4.3 Use description

Use 3 - (not relevant in France)– House mice – professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: juveniles and adults
Field(s) of use	Indoor indoor
Application method(s)	Method: Bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequencies	Application Rate: One bait point of 50 g bait every 5 metres. Dilution (%): 0 Number and timing of application:

	One bait point of 50 g bait every 5 metres.
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>(In France only : minimum pack size of 5 kg)</p> <p>PROTECT SENSATION is supplied in loose blocks of 20, 25 or 50 g. Loose blocks are packed in:</p> <ul style="list-style-type: none"> - PP bucket (5 to 8 kg) - PE bag (5 to 25 kg).

4.3.1 Use-specific instructions for use

- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.3.2 Use-specific risk mitigation measures

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4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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4.4 Use description

Use 4 - (not relevant in France)– Rats – professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: Rattus norvegicus Common name: Brown rat Development stage: juveniles and adults</p> <p>Scientific name: Rattus rattus Common name: Roof rat Development stage: juveniles and adult</p>
Field(s) of use	<p>Indoor</p> <p>Indoor</p>
Application method(s)	<p>Method: Bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequencies	<p>Application Rate: - High infestation: 200 g of bait per baiting point every 7 metres. - Low infestation: 200 g of bait per baiting point every 10 metres. Dilution (%): 0 Number and timing of application: - High infestation: 200 g of bait per baiting point every 7 metres. - Low infestation: 200 g of bait per baiting point every 10 metres.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>(In France only : minimum pack size of 5 kg)</p>

PROTECT SENSATION is supplied in loose blocks of 20, 25 or 50 g. Loose blocks are packed in:

- PP bucket (5 to 8 kg)
- PE bag (5 to 25 kg).

4.4.1 Use-specific instructions for use

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.4.2 Use-specific risk mitigation measures

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4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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4.5 Use description

Use 5 - (not relevant in France)– House mice and/or rats – professionals – outdoor around buildings

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mice Development stage: Adults and juveniles Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: Adults and juveniles Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: Adults and juveniles
Field(s) of use	Outdoor Outdoor around buildings
Application method(s)	Method: Bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequencies	Application Rate: Rats (<i>Rattus norvegicus</i> and <i>Rattus rattus</i>) - High infestation: 200 g of bait per baiting point every 7 metres. - Low infestation: 200 g of bait per baiting point every 10 metres. Mice (<i>Mus musculus</i>) - One bait point of 50 g bait every 5 metres. Dilution (%): 0 Number and timing of application: Rats (<i>Rattus norvegicus</i> and <i>Rattus rattus</i>) - High infestation: 200 g of bait per baiting point every 7 metres. - Low infestation: 200 g of bait per baiting point every 10 metres. Mice (<i>Mus musculus</i>) - One bait point of 50 g bait every 5 metres.
Category(ies) of users	Professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (In France only : minimum pack size of 5 kg) PROTECT SENSATION is supplied in loose blocks of 20, 25 or 50 g. Loose blocks are packed in: - PP bucket (5 to 8 kg) - PE bag (5 to 25 kg).

4.5.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.5.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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5. General directions for use

5.1. Instructions for use

FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

FOR TRAINED PROFESSIONAL ONLY- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

FOR PROFESSIONALS ONLY Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

FOR PROFESSIONALS ONLY Remove the remaining bait or the bait stations at the end of the treatment period.

5.2. Risk mitigation measures

FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").

FOR TRAINED PROFESSIONAL ONLY

- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

FOR TRAINED PROFESSIONAL ONLY

- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- FOR PROFESSIONAL ONLY To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [Where relevant, specify if more frequent or daily inspection is required].
- FOR PROFESSIONAL ONLY Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- FOR PROFESSIONAL ONLY. The product information (i.e. label and/or leaflet) shall clearly show that:
 - the product shall not be supplied to the general public (e.g. "for professionals only").
 - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
 - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- FOR PROFESSIONAL ONLY Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
 - Dermal exposure, wash skin with water and then with water and soap.
 - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
 - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]"
- Hazardous to wildlife.

5.4. Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 2 years.

6. Other information

- (in France only : The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance Bromadiolone. Results of the resistance monitoring must be submitted at the renewal of the product.)
- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.
- The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management at the renewal of the product's authorization